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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,032	08/28/2003	Purnendu K. Dasgupta	067407-5116US	1527
67374 7590 09/17/2008 MORGAN, LEWIS & BOCKIUS, LLP ONE MARKET SPEAR STREET TOWER			EXAMINER	
			TURK, NEIL N	
SAN FRANCISCO, CA 94105			ART UNIT	PAPER NUMBER
			1797	
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			09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Commence	10/653,032	DASGUPTA ET AL.				
Office Action Summary	Examiner	Art Unit				
	NEIL TURK	1797				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timulated and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	J. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 24 Ju	<u>ıly 2008</u> .					
2a) This action is <b>FINAL</b> . 2b) ⊠ This	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
•	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-10,12-26 and 28</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) <u>1-10,12-24,26 and 28</u> is/are rejected.						
· <u> </u>	7)⊠ Claim(s) <u>25</u> is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>09 April 2008</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
coo the attached actained control a list of the continued copies het received.						
Attachmont/ol		i i				
Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	5)  Notice of Informal P 6) Other:	atent Application				
Kalaba da Kata						

#### **DETAILED ACTION**

### Remarks

This Office Action fully acknowledges Applicant's remarks filed on July 24<sup>th</sup>, 2008. Claims 1-10, 12-26, and 28 are pending. Claims 11 and 27 have been cancelled.

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 24<sup>th</sup>, 2008 has been entered.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear in what relative relation the treatment channel extends so as form the respective dispositions of the liquid

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interfaces. Claim 23 recites, "...in which said the flow-through treatment channel extends substantially horizontally, wherein said liquid interface is disposed horizontally". Claim 24 recites, "...in which said flow-through treatment channel extends substantially horizontally, wherein said liquid interface is disposed substantially vertically". The recitations of claims 23 and 24 are unclear as both recitations are drawn to relative descriptions with respect to the disposition of the treatment channel extending, in both cases, horizontally, and the resultant liquid interface being disposed horizontally and vertically, respectively. As the disposition of the liquid interface being "disposed horizontally" and "disposed vertically" are drawn to relative dispositions, both dispositions may be said to be met for a horizontally disposed flow-through treatment channel that takes the sample and carrier stream in parallel. With regard to claim 23, does Applicant intend to recite the case where the liquids flow one on top of the other, thereby establishing a horizontal liquid boundary interface between them? With regard to claim 24, does Applicant intend recite the case where the liquids flow side-by-side in a parallel fashion to as to form a vertical liquid boundary interface between them? Appropriate clarification is required.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

<sup>(</sup>b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 4-9, 12-21, and 23, 24, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Yager (5,971,158).

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Yager discloses an absorption-enhanced differential extraction device for use in affinity chromatography. Yager discloses a device and method for extracting desired particle from a sample stream containing the desired particles. Yager discloses that the device has a sample stream inlet, an extraction stream inlet, and an extraction channel (treatment channel) in fluid communication with the sample stream inlet and extraction stream inlet. Yager discloses that the extraction channel is for receiving a sample stream (such as those listed in lines 1-17, col. 8) in adjacent laminar flow with an extraction stream (comprised of an organic solvent, see lines 17-29, col. 7), wherein the extraction channel is provided with a sequestering material (matrix ion species capture material) to capture desired particles (particles defined to include ions, see lines 19-26, col. 6). Yager further discloses that a bi-product stream outlet in fluid communication with the extraction channel receives a by-product stream comprising at least a portion of the sample stream from which desired particles have been extracted (concentration lower at the outlet than at the inlet). A product outlet in fluid communication with the extraction channel receives a product, which has the sequestering material and at least a portion of the desired particles (abstract). Yager discloses that the sequestering material can be present in the extraction steam prior to the extraction stream's being introduced into the extraction channel, or the sequestering material can be added to the extraction stream by suspending or dissolving the sequestering material in a liquid

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which is introduced into the extraction stream (lines 40-46, col. 4). Yager also discloses that the sequestering material provides for increased diffusion of the desired particles (lines 47-52, col. 5). Yager also discloses that the sample and extraction streams are kept in contact in the extraction channel for a period of time sufficient to allow at least an analyzable quantity, and even small amounts of analytes present may be detected by spectroscopic and other means (line 53, col. 9 – line 5, col. 10). Yager further discloses that the invention may be utilized as a sample pretreatment system for an analytical system including sensing means for detecting desired particles in the product and byproduct streams. Yager discloses separating the sample stream from the carrier liquid stream exiting the treatment channel prior to detection within the product stream 13 (cols. 13&14, fig. 3). Yager discloses detection means include optical means such as spectroscopic equipment, and means for detecting fluorescence, chemical indicators, and also any magnetic resonance equipment or other means known to detect the presence of analyte particles such as ions (lines 36-57, col. 11). Yager further discloses various embodiments of extraction devices in columns 13-15.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.

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- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 12-24, 26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocklin (4,751,189) in view of Yager.

Rocklin discloses a method of ion chromatography. Rocklin discloses that the system is useful for determining a large number of ionic species, such as anions and cations. Rocklin discloses that a suitable sample includes surface waters, chemical wastes, body fluids, and beverages such as fruits and wines and drinking water. Rocklin discloses that the term ionic species includes species in ionic form and components of molecules, which are ionizable under the conditions of the system (lines

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53-62, col. 2). Rocklin shows in figure 1 an eluent reservoir 14 and sample 13 injected to a chromatographic separation means, such as a chromatographic column 10 which is packed with a separation medium, such as an ion-exchange resin. Rocklin discloses that arranged in series with the column 10 is a suppressor means 11 serving to suppress the conductivity of the eluent from column 10 but not the conductivity of the separated ions (lines 13-34, col. 3, fig. 1). The effluent from suppressor means 11 is directed to a detector in the form of a conductivity cell 12 for detecting all of the resolved ionic species (lines 35-54, col. 3). Rocklin discloses that in one embodiment of the suppressor device 17, effluent from the chromatographic column is directed through the effluent flow channel 26 (treatment channel) bounded on both sides by ion-exchange membranes 27, and the ion-exchange membranes are preferably permeable to ions of the same charge as the exchangeable ions of the membrane and resists permeation of ions of opposite charge. Rocklin further discloses that the membranes are simultaneously contacted on their outersides with the regenerate flowing in the opposite direction through the regenerate flow channels 28. Ions extracted from the effluent (sample stream) at the active ion-exchange sites of the membranes are diffused through the membranes and are exchanged with ions of the regenerate (carrier stream), and thus diffused ultimately into the regenerate (lines 8-44, col. 4). Rocklin discloses that a suitable regenerate solution is dilute sulphuric acid (lines 28-37, col. 5).

Rocklin does not disclose a matrix ion species capture material included in the carrier stream.

Yager has been discussed above.

It would have been obvious to modify Rocklin to include a sequestering material in the carrier stream such as taught by Yager in order to provide a means for increasing diffusion of the desired particles while no longer requiring the added elements of the ion exchange membranes in the flow channels.

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Claims 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager in view of Cais et al. (4,510,058), hereafter Cais.

Yager has been discussed above.

Yager discloses the use of various solvents for the carrier liquid. Yager also discloses various sample streams for use within the device that are immiscible with the various organic solvents disclosed. Yager does not specifically disclose any specific pairs of solvent and sample stream which are immiscible with each other.

Cais discloses a column chromatography technique. Cais discloses that the dynamic chromatography can be utilized also in liquid ion exchangers, such as in liquid-liquid extraction systems. Cais discloses that liquid-liquid extraction operates in a manner by interchange of ions at the interface between an aqueous solution and an immiscible solvent with negligible distribution of the extractant to the aqueous phase (lines 3-10, col. 8).

It would have been obvious for Yager to choose a given solvent and a sample stream that is immiscible with the given solvent such as taught by Cais in order to provide a liquid-liquid extraction system for interchange of ions in which there is negligible distribution of the extractant to the aqueous phase.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager.

Yager does not disclose detecting the one analyte ion species in said sample stream.

It would have been obvious to modify Yager to detect the one analyte ion species in the sample stream so as to provide a more accurate and precise detection of the one analyte ion species. This is seen as not all of the analyte ion species may diffuse across to the carrier stream (method disclosed by Yager), thereby leaving behind analyte ion species in the sample stream and altering the true concentration of analyte ion species present.

## Allowable Subject Matter

Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record, namely Yager (5,971,158) and Rocklin (4,751,189), do not teach or fairly suggest the method for treating a liquid sample stream including at least one analyte ion species and matrix ion species as recited in claim 12, with the further constitution that the capture material binds said matrix ion species by forming a salt or complex. Yager and Rocklin in view of Yager disclose the binding of the analyte

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ion species to the capture material to form a complex in the product stream for detection and do not suggest binding the matrix ion species (i.e. the undesired particles) to the capture material. Further, Seidel et al. (6,153,393) discloses providing a reagent to eliminate interference by nonspecific interactions in immunoassays to avoid false-positive detection reactions. Seidel discloses a capture material for binding and forming a complex with the analyte ion species in order to reduce interference and false detection results, and does not teach or fairly suggest eliminating such interference by binding the matrix ion species (i.e. the undesired particles for detection) to the reagent (capture material).

## Response to Arguments

Applicant's arguments filed September 24<sup>th</sup>, 2007 have been fully considered but they are not persuasive.

With regards to claims 23 and 24 rejected under 35 USC 112, 2<sup>nd</sup> paragraph, Applicant traverses the rejection. As discussed above, Applicant's amendments to claim 23 and 24 have not removed the clarity issue with respect to the claims.

With regards to **claims 1, 2, 4-9, 11-21, 23-24, and 26-28** rejected under 35 U.S.C. 102(b) as being anticipated by Yager (5,971,158), Applicant argues that Yager does not meet the claim limitations. **With regard to claim 1**, Applicant argues that Yager does not teach detecting the analyte ion species in the sample stream. Examiner asserts that claim 1 does not require the analyte ion species to be detected in general,

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and further does not require the analyte ion species to be detected in the sample stream. Further, Examiner asserts that Applicant's arguments are drawn to process steps and functionalities. Examiner asserts whereas a claim may be defined functionally and/or structurally, a claim (or claims) to an apparatus must be structurally distinguished from the prior art. With regards to the apparatus of claim 1, and its subsequent dependent claims 2 and 4-9, Yager discloses the recited structure in the claims and is thereby capable of the functionalities.

Further, with regard to the method of **claim 12**, Examiner asserts that Yager discloses the steps of the method; Yager discloses flowing the sample stream 2 from an inlet of a treatment channel to an outlet, and flowing an extraction stream 4 (carrier stream) with a sequestering material (matrix ion species capture material) in a substantially parallel manner through the extraction channel 7 (treatment channel) (cols. 5-8+; figs. 1-3+). Applicant argues that the present inventive method of claim 12 calls from the removal of a matrix ion species from an analyte ion species in the sample stream. Applicant argues that the objective in Yager is to remove analyte from the sample stream into the carrier stream. Examiner asserts that the sequestering material (matrix ion species capture material) in the extraction stream of Yager acts to remove analyte ion species in the sample stream and bring them into the extraction stream (carrier stream). Examiner asserts that such a step still involves removing the matrix ion species away from the analyte ion species as one is moved and no longer with the other species.

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With regard to claim 2, Applicant argues that claim 2 recites a detector for the at least one analyte ion species in the sample stream and a fluid conduit providing fluid communication between the sample treatment outlet and the detector with the sample stream flowing through the conduit. Examiner asserts that the recitation with respect to the detector, which reads, "a detector for said at least one analyte ion species in said sample stream" is drawn to a functionality of the detector to detect at least one analyte ion species in the sample stream and does not structurally place the site of the detector to be placed in the sample stream. If Applicant intends that the detector lies within the sample stream, than Applicant must positively recite the structural location of the detector relative to the sample stream and not in functional terms which do not place the detector in a particular place within the device. Examiner asserts that the analyte ions detected in Yager come from the sample stream, and as such the detector(s) recited in Yager have the same functionality of detecting at least one analyte ion species in the sample stream such that the analyte ions come from the sample stream. Examiner further asserts that at least a portion of the sample stream will inherently flow through the conduit.

With regards to claims 1-10, 12-24, 26, and 28 rejected under 35 USC 103(a) as being unpatentable over Rocklin (4,751,189) in view of Yager, Applicant traverses the rejection.

Applicant argues that Rocklin does not disclose a matrix ion species capture material in the carrier stream and there is no reason for the inclusion of such material.

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Examiner argues that, as presented above, it would have been obvious to modify Rocklin to include a sequestering material in the carrier stream such as taught by Yager in order to provide a means for increasing diffusion of the desired particles while no longer requiring the added elements of the ion exchange membranes in the flow channels. Examiner argues that the combination of Rocklin in view of Yager is not modified with respect to the detection of the ions in any particular stream.

With regards to claims 9 and 21 rejected under 35 USC 103(a) as being unpatentable over Yager in view of Cais et al. (4,510,058), Applicant argues that such a combination is not proper.

Applicant remarks that the advantages of using immiscible sample and carrier liquid streams are set forth at pages 10-12 of the specification. Applicant contends that there is no suggestion in Cais of such advantages of using immiscible liquids. Examiner asserts that it is not required that Cais disclose that of which is disclosed in Applicant's specification at pages 10-12.

Examiner asserts that Yager discloses the use of various solvents for the carrier liquid. Yager also discloses various sample streams for use within the device that are immiscible with the various organic solvents disclosed. Cais discloses that the chromatography technique disclosed can also be utilized in liquid ion exchangers, such as liquid-liquid extraction systems. Cais further discloses that the liquid-liquid extraction operates in a manner by interchange of ions at the interface between an aqueous solution and an immiscible solvent with negligible distribution of the extractant to the

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aqueous phase. Thereby, as Yager discloses a liquid-liquid extraction system and discloses various organic solvents and sample streams for use with the device that are immiscible in such solvents, it would have been obvious to modify the liquid-liquid extraction system of Yager by that of the liquid-liquid extraction of Cais which utilizes a solvent and sample stream that are immiscible with each other, so as to provide for interchange of ions with negligible distribution of the extractant to the aqueous phase.

Applicant's arguments with respect to claims 14-16 have been considered but are most in view of the new ground(s) of rejection as discussed above.

### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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NT /Jill Warden/
Supervisory Patent Examiner, Art Unit 1797